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Display Date 9-3-99
Publication Date 9-7-99
Certifier SNReese

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 522 and 556

Implantation or Injectable Dosage Form New Animal Drugs; Chorionic Gonadotropin

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) filed by Intervet, Inc. The supplemental NADA provides for intramuscular use of chorionic gonadotropin, a freeze-dried powder reconstituted for intramuscular injection in male and female brood finfish as an aid in improving spawning function. The regulations are also amended to establish an acceptable daily intake (ADI) for total gonadotropins.

EFFECTIVE DATE: (*Insert date of publication in the* **Federal Register**.)

FOR FURTHER INFORMATION CONTACT: Joan C. Gotthardt, Center for Veterinary Medicine (HFV–130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7571.

SUPPLEMENTARY INFORMATION: Intervet, Inc., 405 State St., P.O. Box 318, Millsboro, DE 19966–0318, filed supplemental NADA 140–927 that provides for use of Chorulon® (chorionic gonadotropin) freeze-dried powder, reconstituted for intramuscular injection in male and female brood finfish as an aid in improving spawning function. The supplemental NADA is approved as of August 6, 1999, and § 522.1081 (21 CFR 522.1081) is amended to reflect the approval. The basis for approval is discussed in the freedom of information summary.

In addition, data in the supplemental NADA were evaluated to establish an ADI for total gonadotropins. The regulations are amended in part 556 (21 CFR part 556) by adding § 556.304

to provide an ADI for total gonadotropins and to provide that a tolerance for residues of gonadotropins in edible tissues of treated animals is not required. Also, § 522.1081 is amended to add paragraphs referencing related tolerances.

In addition, FDA is removing the footnote in § 522.1081(a)(3). This regulation was footnoted to reflect those conditions of use that were subject to review under the National Academy of Sciences/National Research Council (NAS/NRC) Drug Efficacy Study Implementation (DESI) program and FDA's conclusions based on that review. With the enactment of the Generic Animal Drug and Patent Term Restoration Act of 1986, use of NAS/NRC DESI reviews to support approval of new animal drugs became obsolete.

In accordance with the freedom of information provisions of 21 CFR part 20 and 514.11(e)(2)(ii)), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.33(c) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(iii)), this approval for food-producing animals qualifies for 3 years of marketing exclusivity beginning August 6, 1999, because the supplement contains substantial evidence of the effectiveness of the drug involved, any studies of animal safety or, in the case of food-producing animals, human food safety studies (other than bioequivalence or residue studies) required for approval of the supplement and conducted or sponsored by the applicant. The 3 years of marketing exclusivity applies to use of chorionic gonadotropin freeze-dried powder, reconstituted for intramuscular injection in male and female brood finfish as an aid in improving spawning function.

This rule does not meet the definition of ''rule'' in 5 U.S.C. 804(3)(A) because it is a rule of ''particular applicability.'' Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects

21 CFR Part 522

Animal drugs.

21 CFR Part 556

Animal drugs, Foods.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR parts 522 and 556 are amended as follows:

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 522 continues to read as follows:

Authority: 21 U.S.C. 360b.

2. Section 522.1081 is amended by adding after the word ''intrafollicularly'' the phrase ''in cattle'' in paragraphs (a)(2)(i) and (a)(2)(ii), by adding after the word ''intramuscularly'' the phrase ''in cattle and finfish'' in paragraph (a)(2)(iii), by redesignating paragraph (a)(3) as paragraph (a)(4), by adding new paragraph (a)(3), by revising the heading and by removing the footnote of newly redesignated paragraph (a)(4), by revising newly redesignated paragraph (a)(4)(i), by adding paragraph (a)(5), by redesignating paragraph (b)(3) as paragraph (b)(4), by adding new paragraph (b)(3), by revising the heading of newly redesignated paragraph (b)(4), by removing ''ovualtions'' and adding in its place ''ovulations'' in newly redesignated paragraph (b)(4)(iii) to read as follows:

§ 522.1081 Chorionic gonadotropin for injection; chorionic gonadotropin suspension.

(a) * * *

(3) *Related tolerances.* See § 556.304 of this chapter.

(4) *Conditions of use in cattle*—(i) *Amount.* 10,000 USP units as a single, deep intramuscular injection; 500 to 2,500 USP units for intrafollicular injection; 2,500 to 5,000 USP units intravenously.

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(5) *Conditions of use in finfish*—(i) *Amount.* 50 to 510 I.U. per pound of body weight for males, 67 to 1816 I.U. per pound of body weight for females, by intramuscular injection.

(ii) *Indications for use.* An aid in improving spawning function in male and female brood finfish.

(iii) *Limitations.* May administer up to three doses. The total dose administered per fish (all injections combined) should not exceed 25,000 I.U. chorionic gonadotropin (25 milliliters) in fish intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(b) * * *

(3) *Related tolerances.* See § 556.304 of this chapter.

(4) *Conditions of use in heifers* * * *

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PART 556—TOLERANCES FOR RESIDUES OF NEW ANIMAL DRUGS IN FOOD

3. The authority citation for 21 CFR part 556 continues to read as follows:

Authority: 21 U.S.C. 342, 360b, 371.

4. Section 556.304 is added to subpart B to read as follows:

§ 556.304 Gonadotropin.

(a) *Acceptable daily intake (ADI).* The ADI for residues of total gonadotropins (human chorionic gonadotropin and pregnant mare serum gonadotropin) is 42.25 I.U. per kilogram of body weight per day.

(b) *Tolerances*. A tolerance for residues of gonadotropin in uncooked edible tissues of cattle or of fish is not required.

Dated: 8/24/99

August 24, 1999

Stephen F. Sundlof
Director
Center for Veterinary
Medicine

[FR Doc. 99–???? Filed ??–??–99; 8:45 am]

BILLING CODE 4160–01–F

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